

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effect of Rivaroxaban and Enoxaparin on preventing the venous thromboembolism after spinal surgery

Protocol summary

Study aim

Comparison of the effects of Rivaroxaban and Enoxaparin on the reduction of venous thromboembolism after spinal surgery

Design

A phase 3 Randomized clinical trial, with parallel group designed for 250 patients

Settings and conduct

Patients who underwent spine surgery at Imam Hossein Hospital in Tehran were included in the study to evaluate the effects of rivaroxaban and enoxaparin on reducing post operation deep vein thrombosis and venous embolism. All patients were evaluated after surgery for DVT and PTE by venous Doppler ultrasound and CT angiography of the lungs.

Participants/Inclusion and exclusion criteria

Patients who have undergone spine surgery and have no previous history of venous thromboembolism or cerebrovascular accident.

Intervention groups

Patients after spine surgery were divided into 3 groups, the group receiving Rivaroxaban, the group receiving Enoxaparin and the control group.

Main outcome variables

Deep vein thrombosis; Pulmonary thromboembolism

General information

Reason for update

Supplementary data from the clinical trial was recorded

Acronym

IRCT registration information

IRCT registration number: **IRCT20200808048333N1**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-30, 1402/05/08**

Update count: **1**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Poorya Paryan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

pooryaparyan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

2020-08-22, 1399/06/01

Actual recruitment end date

2022-12-13, 1401/09/22

Trial completion date

empty

Scientific title

Evaluation of the effect of Rivaroxaban and Enoxaparin on preventing the venous thromboembolism after spinal surgery

Public title

Comparison of Rivaroxaban and Enoxaparin for preventing venous thromboembolism after spine surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing spine surgery No previous history of

thromboembolism

Exclusion criteria:

Previous history of venous thromboembolism Pregnancy

History of cerebrovascular accident

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **200**

Actual sample size reached: **220**

Randomization (investigator's opinion)

Randomized

Randomization description

the block randomization method will be used, and 11 blocks of 10 people will be created. Sealed Envelope online software will be used to create random codes. The number of patients in groups A and B in each block is equal, but the random sequence will differ.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All Participants, Investigators, Outcome assessors, Data analyst, and quality controller are blinded. Due to the difference in the form of administration, the double dummy technique was used for blinding, as patients in the enoxaparin group received the injectable form of enoxaparin and placebo tablets, and the patients in the rivaroxaban group received the injectable form of placebo and rivaroxaban tablets. Placebo forms (both tablets and injectable forms) have the same shape, color and packaging as the original drug form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Kudakyar street, Shahid Shahriari Square, Daneshjou
Boulevard, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.SBMU.MSP.REC.1399.411

Health conditions studied

1

Description of health condition studied

Deep Venous Thrombosis And Pulmonary Eembolism

ICD-10 code

I82.4

ICD-10 code description

Acute embolism and thrombosis of deep veins of lower extremity

Primary outcomes

1

Description

Deep Vein Thrombosis

Timepoint

At the begining of the study,14 days after

Method of measurement

Color Doppler Ultrasonography of the lower Extremities

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipient of Rivaroxaban, patients that receive Rivaroxaban (10mg orally) once daily after surgery to prevent venous thromboembolism, until discharged from hospital.In this group, the effects of this drug on thromboembolic events after surgery will be investigated.

Category

Treatment - Drugs

2

Description

Intervention group: Recipient of Enoxaparin, patients that recieve Enoxaparin (40 mg subcutaneous) once daily after surgery to prevent venous thromboembolism, until discharged from hospital.In this group, the effects of

this drug on thromboembolic events after surgery will be investigated.

Category

Treatment - Drugs

3

Description

Control group: no medication

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Hamidreza Khayat Kashani

Street address

Imam hosein hospital, Madani Ave, Nezamabad

City

Tehran

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1617763141

Phone

+98 21 7343 0000

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hamidkhayat@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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1983963113

Phone

+98 21 2243 9770

Email

Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamidreza Khayat Kashani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared.

When the data will become available and for how long

Access period starts 6 months after the publication of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For scientific and academic studies

From where data/document is obtainable

Contact with Shahid beheshti university of medical sciences(info@sbmu.ac.ir) and Dr.hamidreza khayat kashani (hamidkhayat@yahoo.com).

What processes are involved for a request to access data/document

After approval from the University Vice Chancellor for Research, it is possible to share data.

Comments